Complete Summary

GUIDELINE TITLE

Management of helicobacter pylori infection.

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Management of helicobacter pylori infection. Singapore: Singapore Ministry of Health; 2004 Sep. 25 p. [29 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
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SCOPE

DISEASE/CONDITION(S)

Helicobacter pylori infection

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology

Internal Medicine
Oncology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations on

- Who should be tested and treated for Helicobacter pylori infection
- Treatment regimens for patients with Helicobacter pylori infection

TARGET POPULATION

- Patients with suspected or diagnosed Helicobacter pylori infection, including patients with:
    - Gastric ulcer (GU) or duodenal ulcer (DU)
    - History of peptic ulcer bleeding or perforation
    - Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
    - Early gastric cancer lesions
    - Noncardiac gastric cancer
    - Gastro-esophageal reflux disease (GERD)
    - Dyspepsia
- First degree relatives of gastric cancer patients

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Serological tests (detection of immunoglobulin G antibodies to Helicobacter pylori)
2. Urea breath test for H. pylori
3. Biopsy urease test
4. Histology (staining of biopsy specimen with hematoxylin and eosin)
5. Culture and stool antigen test for H. pylori
6. Gastrointestinal endoscopy
7. Post treatment testing for H. pylori
8. Helicobacter pylori cytotoxin associated gene A (CagA) protein status
9. Endoscopic ultrasonography (EUS)

Note: Screening for H. pylori in certain population groups was considered but not recommended.

Treatment/Management

Combination Regimens

1. Proton pump inhibitor (PPI)* + clarithromycin + amoxicillin
2. PPI + clarithromycin + metronidazole (tinidazole as alternative)
3. PPI + amoxicillin + metronidazole
4. Colloidal bismuth subcitrate + metronidazole + tetracycline
5. PPI + colloidal bismuth subcitrate + metronidazole + tetracycline

*Proton pump inhibitors currently available include omeprazole, lansoprazole, rabeprazole, pantoprazole, and esomeprazole.

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests for Helicobacter pylori (H. pylori)
- H. pylori eradication rate
- Relief of reflux symptoms in patients with gastro-esophageal reflux disease (GERD)
- Prevention of gastric cancer
- Remission of lymphoma in patients with gastric mucosa-associated lymphoid tissue (MALT) lymphoma

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level Ia: Evidence obtained from meta-analysis of randomised controlled trials

Level Ib: Evidence obtained from at least one randomised controlled trial

Level IIa: Evidence obtained from at least one well-designed controlled study without randomisation

Level IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

Level III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies

Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

Grade B (evidence levels IIa, IIb, III): Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation

Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the level of the evidence and the grade of recommendation. Definitions of the grades of the recommendations (A, B, C, Good Practice Points) and level of the evidence (Level I-Level IV) are presented at the end of the Major Recommendations field.

Diagnosis of Helicobacter pylori (H. pylori) infection

A - Serological tests for Helicobacter pylori (H. pylori) infection should be locally validated and have a sensitivity and specificity of at least 90% (Grade A Level Ib)

A - The urea breath test (UBT) is a reliable test for H. pylori before and after treatment. (Grade A, Level Ib)

A- Biopsy urease test is the endoscopic investigation of choice for H. pylori infection. (Grade A, Level Ib)

B - Culture is an impractical means of diagnosing H. pylori infection. (Grade B, Level IIa)

B - Post-treatment testing is desirable. (Grade B, Level IIa)

A - Stool antigen test (HpSA). (Grade A, Level Ia)

Treatment of H. pylori Infection

A - All gastric and duodenal ulcer patients who are infected with H. pylori should be treated with eradication therapy. Patients with a history of ulcer bleeding or perforation should also be treated. (Grade A, Level Ia)

A - Routine testing for, and treatment of, H. pylori infection is not recommended prior to initiating treatment with nonsteroidal anti-inflammatory drugs (NSAIDs). For patients with a past history of peptic ulcer disease or ulcer complications (perforation, bleeding, or obstruction), testing for and treatment of H. pylori infection is recommended. (Grade A, Level Ib)

GPP - In patients requiring long-term NSAID therapy, who have a current or recent history of dyspepsia, appropriate investigation of the dyspepsia and treatment for H. pylori infection, if documented to be present, is recommended. (GPP)

A - Patients with nonulcer dyspepsia (i.e., dyspepsia after investigation) can be considered for treatment of H. pylori infection on a case-by-case basis. (Grade A, Level Ia)

GPP - Patients who are first degree relatives of gastric cancer patients should be treated for H. pylori infection. (GPP)

C - Patients with gastro-oesophageal reflux disease and who require long-term proton pump inhibitor (PPI) therapy should be treated for H. pylori infection. (Grade C, Level IV)

H. pylori Infection and Gastric Cancer

C - It is recommended that H. pylori infection be treated in patients following resection of early gastric cancer. Screening asymptomatic individuals for H. pylori infection as a means of reducing the incidence of gastric cancer is not currently recommended. (Grade C, Level IV)

B - Treatment for H. pylori infection is recommended in patients with low-grade gastric mucosa-associated lymphoid tissue lymphoma. (Grade B, Level III)

H. pylori Infection and Dyspepsia

C - Screening all dyspeptic patients for H. pylori infection is not recommended. (Grade C, Level IV)

GPP - It is possible to identify dyspeptic patients who require early endoscopy based on the incidence of gastric cancer in a particular country; the presence of alarm features such as weight loss, bleeding, and anaemia; the age of presentation of the patient with the cut-off depending on the age-specific incidence of gastric cancer in that country. (GPP)

A - Dyspeptic patients, after full investigation (i.e., non-ulcer dyspepsia) may be offered H. pylori eradication therapy. (Grade A, Level Ia)

Drug Regimens for H. pylori Infection

A - In 1998, drug regimens for H. pylori infection could produce an eradication rate of 90% or greater on a per-protocol analysis and 80% or greater on an intent-to-treat analysis in properly designed clinical trials. Based on these criteria, the following combination regimens are recommended:

> PPI in standard dose[(1)] + clarithromycin 500 mg + amoxicillin 1,000 mg

PPI in standard dose[(1)] + clarithromycin 500 mg + metronidazole 400 mg

[(1)]Proton Pump Inhibitor: lansoprazole 30 mg, omeprazole 20 mg

(Grade A, Level Ia)

Each of the above regimens should be given for seven days on a twice-daily basis.

A - If clarithromycin is not available, either of the following two regimens may be considered:

PPI in standard dose twice daily + Amoxicillin 1,000 mg twice daily + Metronidazole 400 mg twice daily. For 7 days

Colloidal bismuth subcitrate 120 mg four times daily + Metronidazole 400 mg twice daily + Tetracycline 500 mg four times daily. For 14 days

(Grade A, Level Ib)

A - In the event of a treatment failure with a PPI regimen containing clarithromycin, "salvage therapy" is required. (Grade A, Level Ib) (Malfertheiner et al., 2002)

A regiment for use after initial treatment failure is:

PPI in standard dose twice daily + Colloidal bismuth subcitrate 120 mg four times daily + Metronidazole 400 mg twice daily + Tetracycline 500 mg four times daily

Definitions:

Grades of Recommendations

Grade A (evidence levels Ia, Ib): Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

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Grade C (evidence level IV): Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality

Good Practice Points: Recommended best practice based on the clinical experience of the guideline development group

Levels of Evidence

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Level IV: Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

CLINICAL ALGORITHM(S)

A clinical algorithm is provided for the management of new onset uninvestigated dyspepsia

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

- Appropriate diagnosis, risk assessment, treatment, and prevention of Helicobacter pylori (H. pylori) infection
- Better outcomes and improved quality of life of patients with H. pylori infection

POTENTIAL HARMS

- In children false-negative tests for Helicobacter pylori (H. pylori) infection can occur from a few weeks to a few months after an infection but before an immune response occurs
- Treatment of H. pylori infection in patients with nonulcer dyspepsia may aggravate symptoms in the short-term

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are not intended to serve as a standard of medical care. Standards of medical care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances and patterns of care evolve.
- The contents of this publication are guidelines to clinical practice, based on the best available evidence at the time of development. Adherence to these guidelines may not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care. Each physician is ultimately responsible for the management of his/her unique patient in the light of the clinical data presented by the patient and the diagnostic and treatment options available.
- Users should supplement the guidelines with any new evidence that has emerged since publication.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The desired clinical outcome is eradication of Helicobacter pylori (H. pylori) in all patients in whom eradication is of proven benefit, i.e. patients with complicated or uncomplicated H. pylori-associated peptic ulcer disease.

Audit should look at:

- Proportion of patients with upper gastrointestinal bleeding that are tested for H. pylori infection
- The proportion of patients with bleeding peptic ulcer due to H. pylori infection that are offered eradication therapy.
- Proportion of patients with peptic ulcer disease receiving long-term anti-secretory treatment that are offered eradication therapy.
- Proportion of patients treated for gastric ulcer or complicated duodenal ulcer with H. pylori infection, who demonstrate cure of infection.
- Proportion of peptic ulcer disease patients with H. pylori infection that relapse after treatment.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Singapore Ministry of Health. Management of helicobacter pylori infection. Singapore: Singapore Ministry of Health; 2004 Sep. 25 p. [29 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Sep

GUIDELINE DEVELOPER(S)

Gastroenterological Society of Singapore - Medical Specialty Society
Singapore Ministry of Health - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Singapore Ministry of Health (MOH)

GUIDELINE COMMITTEE

Workgroup on the Management of Helicobacter Pylori Infection

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Singapore Ministry of Health Web site.

Print copies: Available from the Singapore Ministry of Health, College of Medicine Building, Mezzanine Floor 16 College Rd, Singapore 169854.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on November 26, 2004.

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Date Modified: 2/14/2005